

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Daniel Kuzmich *et al.*

Examiner: D. Margaret Seaman

U.S. Patent No. 7,579,469

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Serial No.: 10/739,208

Group Art Unit: 1625

Filed: December 18, 2003

Docket: 9/272

Customer No.: 28509

Confirmation No.: 1223

For: GLUCOCORTICOID MIMETICS, METHODS OF MAKING THEM,  
PHARMACEUTICAL COMPOSITIONS, AND USES THEREOF

**RECONSIDERATION OF APPLICATION FOR PATENT TERM ADJUSTMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is a request for reconsideration of the patent term adjustment indicated in the Issue Notification and relevant patent and is being filed as an Application for Patent Term Adjustment pursuant to 37 C.F.R. § 1.705(b).

The PTO calculation in the Notice of Allowance was 303 days. Applicants timely filed an Application for Patent Term Adjustment on May 29, 2009. In a Decision on Application for Patent Term Adjustment dated July 20, 2009 (enclosed), the PTO held the decision in abeyance until after the patent issued. In the Issue Notification of August 5, 2009 and the relevant patent, the PTO revised the patent term adjustment to 611 days.

Applicants submit that the correct calculation is 1026 days, as detailed below. This request is being filed within two months of the issue date of the patent and therefore this request is timely filed according to the Decision on Application for Patent Term Adjustment dated July 20, 2009.

The Decision on Application for Patent Term Adjustment dated July 20, 2009, also advised that

no additional fee would be required for this submission. Should any fee be required, however, Applicants herewith authorize the PTO to charge such fee(s) to Applicant's Deposit Account No. 02-2955.

Pursuant to 37 C.F.R. § 1.705(b)(2)(i), below is an indication of the correct patent term adjustment and the basis or bases under § 1.702 for the adjustment:

Correct Patent Term Adjustment (PTA) = 1026 days

Bases for the above PTA

(A) 416 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1);

plus

(B) 731 days under 37 C.F.R. §§ 1.702(b) and 1.703(b);

minus

(C) 121 days under 37 C.F.R. § 1.704(b);

Total PTA = (A) 416 days + (B) 731 days - (C) 121 days = 1026 days

Pursuant to 37 C.F.R. § 1.705(b)(2)(ii), below is an indication of the relevant dates specified in 37 C.F.R. § 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703 (f) to which the patent is entitled:

(A) 416 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1)

The 416 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1) is calculated based on the following dates:

(1) The day after the date that is 14 months after the date on which the application was filed under 35 U.S.C. 111(a) = 19 February 2005

(2) The date of mailing of the first action under 35 U.S.C. 132 = 10 April 2006

(3) The number of days beginning on 19 February 2005 and ending on 10 April 2006 = 416 days

(B) 731 days under 37 C.F.R. §§ 1.702(b) and 1.703(b)

The 731 days under 37 C.F.R. §§ 1.702(b) and 1.703(b) is calculated based on the following dates:

(1) The day after the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) = 19 December 2006

(2) The filing of an RCE= 19 December 2008

(3) The number of days beginning on 19 December 2006 and ending on 19 December 2008 = 731 days

The PTA specified in 37 C.F.R. § 1.703(f) to which the patent is entitled

As specified in 37 C.F.R. § 1.703(f), the term of a patent entitled to adjustment under § 1.702 and § 1.703 shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of § 1.703, to the extent such periods are not overlapping, less the sum of the periods calculated under § 1.704.

For the instant application the sum of the periods under paragraphs (a) through (e) of § 1.703 is 1147 days, calculated as follows:

(A) 4161 days delay under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1);  
plus

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<sup>1</sup> The PAIR patent term adjustment calculations reflect an 8 day delay under 37 C.F.R. § 1.703(2)(1). An after final response was filed on 6 November 2006 to which a final rejection was mailed on 14 March 2007, which was 8 days beyond the 4 month period specified in § 1.703(2) - thus, a 8 day reduction. However, this period of delay overlaps the delay calculated under 37 C.F.R. § 1.703(b) and for purposes of this application for patent term adjustment the 8 day period has not been counted.

(B) 731 days delay under 37 C.F.R. §§ 1.702(b) and 1.703(b).

The two periods of delay specified above are not overlapping, since the first period of delay under 7 C.F.R. § 1.703(a)(1) ended on 10 May 2006 (when the first office action was mailed) and the second period of delay under 37 C.F.R. § 1.703(b) did not start until 19 December 2006 (the day after the date that is 3 years after the date on which the application was filed). Thus, there were no days falling within both periods of delay and therefore no overlap<sup>2</sup>.

For the instant application the sum of the periods calculated under 37 C.F.R. § 1.704 is 121 days, as follows:

(C) 32 days under 37 C.F.R. § 1.704(b). An Office Action was issued on 5 July 2006, to which a response was not filed until 6 November 2006, which was 32 days beyond the 3 month period specified in § 1.704(b) - thus, a 32 day reduction

plus

89 days under 37 C.F.R. § 1.704(b). An Office Action was issued on 22 February 2008, to which a response was not filed until 19 August 2008, which was 89 days beyond the 3 month period specified in § 1.704(b) - thus, an 89 day reduction.

Therefore, the PTA specified in 37 C.F.R. § 1.703(f) to which the patent is entitled is 1026 days, calculated as follows:

1147 days (the sum of the periods under paragraphs (a) through (e) of § 1.703)

minus

121 days (the sum of the periods calculated under § 1.704)

=1026 days

With respect to 37 C.F.R. § 1.705(b)(2)(iii), the resulting patent issued on the instant application is subject to a Terminal Disclaimer over pending application number 10/947,420 which was filed 22 September 2004.

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<sup>2</sup> See Wyeth v. Dudas, 580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008)

With respect to 37 C.F.R. § 1.705(b)(2)(iv), there were circumstances during prosecution of the instant application constituting failure to engage in reasonable efforts to conclude processing or examination of the application under 37 C.F.R. § 1.704. These circumstances are as outlined above under (C) resulting in the following PTA reductions: 121 days under 37 C.F.R. § 1.704(b) [for response filed 19 August 2008 and for a response filed 6 November 2006], for a total of PTA reduction of 121 days.

Accordingly, Applicants respectfully request that the PTA specified in the Issue Notification of August 5, 2009 and the relevant patent (stated therein to be 611 days) be corrected to 1026 days for the reasons as outlined above.

The Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 02-2955.

Respectfully submitted,

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